

SPL ER/DL Team

Feb 16, 2011

Minutes

NEW Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Michelle Halliez

1. Follow-up on status of Drug Listing required for foreign API manufacturers and foreign drug product manufacturers - Marilyn Maxwell
 - a. To be discuss at the meeting being planned with DRLS, in mid March.
2. When an NDC is removed but the product code remains active (ie, other NDCs for different pack sizes remain listed) – will that removed NDC be removed/discontinued from the NDC directory at time of removal or when the whole product code is delisted? Or neither? - Jackie Mohns, BMS.
 - a. Dragan: The NDC number is supposed be removed from the NDC directory at the time the NDC is removed from the SPL
 - b. If the NDC code is not removed, then you should contact the eDRLS website to ask that it be removed.
3. We have a foreign TPM who is in the process of registering electronically, but they have no US facility or headquarters – who would be a neutral US Agent for this establishment/company? - Jackie Mohns, BMS
 - a. They will have to hire one. Do a Google search on “US Agent”. Some of the SPL vendors act as US agent.
4. What is the purpose of the FDA SPL webpage? I heard that ALL SPL files are on it...even those which have been removed from DailyMed. Apparently, FDA has no way of filtering deleted files. - Jean Kirkeleit-Davis
 - a. <http://labels.fda.gov/>
 - b. FDA site has only R4 labels. Doesn't have all versions of SPL – only get the most current version.
 - i. Daily Med stylesheet is different from FDA (eg doesn't display suffix).
 - ii. FDA site displays the SPL using its own stylesheets etc – ie can see SPL from FDA perspective.
 - iii. The two systems should be running in parallel.
 - c. SPL will appear on FDA site -- even if there is an end date and has been moved to archive on Daily Med.
 - d. If you submit an SPL with a future date (in order to import the product), where will it appear?
 - i. FDA label repository: no
 - ii. Daily med: no
 - iii. Drugs@fda: reference appears, but the label doesn't appear.
 - e. If you submit an SPL with a market end date, where will it appear.
 - i. FDA label repository: yes
 - ii. Daily med: archive

iii.

5. Other related questions:
 - a. PLAIRs, if you try to submit an SPL for an unapproved product/NDA file, the SPL does not pass validation. The validation checks against approved NDAs. The the SPL will fail if NDA is not approved.
 - i. Post meeting note: Per Lonnie, sponsor should request a manual override
 - b. If a product is being drug listed in order to pull it from DailyMed, and the NDA has already been discontinued/withdrawn, those drug listings are currently bouncing.
 - i. Post meeting note: Per Lonnie, sponsor should request a manual override
6. How do the new marketing categories differ from some already listed? For example: NDA vs Approved drug for PLD. - Jean Kirkeleit-Davis
 - a. These are further granularity on existing terms. These codes were requested by DRLS.
 - b. Very specific to establishments who are manufacturing and only providing the material to a PLD.
 - c. We have asked DRLS to discuss this at our upcoming teleconference.
7. Does anyone know if I can pull down a list of SPLr3 files and SPLr4 files posted on DailyMed for Hospira? I am trying to determine who many of my SPL files are r4 vs r3. - Jean Kirkeleit-Davis
 - a. Search NLM using your labeler code. Will get list of everything that has that string. Copy and start looking.
 - b. Spreadsheet on the FDA label site (downloadable SPL data) will give R4.
 - c. Can compare FDA to NLM list to eliminate R4 -- get to R3.
8. Has anyone found a way to find all business operations for a specific establishment
 - a. Ask the supplier how they registered.
 - b. Lonnie will help.
 - c. Work through FOI—for all establishments and their business operations.
 - d. If you overlist the operations, the error message will be specific for the operations.
9. Opening up and printing an SPL in IE – depending on your IE settings, the background color may be red. This is an inadvertent error and will be fixed the next time the stylesheet is loaded.
 - a. Workaround: If you get a red background when you try to print from IE, change your settings in IE by – Tools/Internet Options/Advanced...and scroll down and uncheck the Print option checkbox titled “Print background colors and images.”
10. ID error being seen by GSK: Every file submitted within the last few days has been coming back with an ID error.
 - a. There is a new validation rule that requires a new GUID every time the section changes and there is a new effective date. This doesn't seem to be the problem.
 - b. Jennifer/Terry are investigating and will let us know why this is happening.
11. Mobile version of the Daily Med is available for your remote access devices.

Upcoming Meetings being planned:

- Discussion with CMS: Michelle is organizing
- Discussion with First DataBank: Jessica is organizing
- Discussion with DRLS: Pat Cowall is coordinating this meeting, and we are working for a date in March.